

Responses and Comments

The applicant would reiterate or supplement the prior comments in this writing. The test is for a protein that binds 25-hydroxy vitamin D. That is the function of the test. It was developed to determine salt sensitivity, but could be used for any purpose wherein binding of 25-hydroxy vitamin D by a protein is at issue. The claim has been rewritten to more clearly indicate that. Should such binding activity have any other significance, the different significance would not alter the fact that binding 25-hydroxy vitamin D by a protein is under investigation.

Both independent method and kit claims have been rewritten and the prior independent claims cancelled. Expanding on the arguments of the original Response filed January 21, 2009, the two samples are used because when the unlabeled 25-hydroxy vitamin D binds to the protein and is present only in one of the samples or sample sets, the sample has less, if any, protein capable of binding available to bind to the labeled 25-hydroxy vitamin D. The sample lacking the unlabeled 25-hydroxy vitamin D would then show greater binding with the labeled 25-hydroxy vitamin D than the sample with the unlabeled, since all binding protein would have to interact with the labeled 25-hydroxy vitamin D.

The examiner has questions use of terminology, namely, that "vitamin D" and sometimes "vitamin D₃" seemingly interchangeably and it is unclear what is desired." It is believed the claim 12 better indicates the specific use of the term, the specific reagents being used in the assay (present in the kit) being the D₃.

The discussion relating to the references as provided on January 21 are deemed appropriate and is not reiterated herein.

Regarding the kit claim, kits with reagents for studying proteins wherein the target protein is studied do sometimes contain charcoal and antibodies for scrubbing "loose" protein. However, the charcoal for scrubbing without an antibody is appropriate in this kit, since the protein is coming from the urine, and no antigen-antibody reaction is being undertaken. The novelty lies in that this is a binding test, and not a test for the protein as such. Hence, no protein in the form of antibodies or proteins that are not antibodies exists. There is no need to identify amount of any protein, but only binding power, so antibodies usually used in tests are not needed, only charcoal to scrub out proteins. In fact, there would also be no need for unlabeled

25-hydroxy vitamin D if it were only proteins rather than binding activity (previously not considered in any reference) if only the amount of protein were being considered.

If any further discussion would facilitate prosecution, the Examiner is invited to call the undersigned at 703 425 8405.

Respectfully submitted,



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